Presentation at 2012 SOPHE Annual Meeting -- Fries Award Recipient

Slide 1/Title Slide: What Does it Mean to Be Pragmatic?

Opportunities and Challenges for Pragmatic Approaches
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Slide 2: NCI Implementation Science Team Vision

To achieve the rapid integration of scientific evidence, practice, and policy, with the ultimate goal of improving the impact of research on cancer outcomes and promoting health across individual, organizational and community levels.
http://cancercontrol.cancer.gov/is/

Slide 3: Pragmatic Methods, Measures and Models

- Overview and Methods Issues:
  - Pragmatic Trials
  - Types of Evidence Needed:"2 R's and RCT"
    - Measurement Issues:
      - Criteria for Pragmatic Measures
      - Example applications
    - Models:
      - Realist perspective, Evidence Integration Triangle
    - Opportunities and Challenges:

Slide 4: Definitions of Pragmatic

Wikipedia on Pragmatism: "a philosophical tradition centered on the *linking of practice and theory"*
Miriam Webster adds: Pragmatic approaches use a process where theory is extracted from practice, and applied back to practice to form what is called *intelligent practice.*

Slide 5: Why is Pragmatic Research Needed?

- Not reaching those with complex problems and those most in need
- Not testing in settings and with staff that are typical to most public health or clinical situations
- Not addressing issues important to practitioners, policy makers, and citizens/families
- Many "evidence-based"; treatment not feasible in most real-world settings
- Bottom Line— *research not seen as RELEVANT*

Rothwell PM. *Lancet* 2005;365:82-93.

Slide 6: Most Common Research Translation: Bench to Bookshelf

[Image] Clinician looking at vial and writing notes with arrow pointing to books covered in cobwebs [End Image]

Slide 7: Pragmatic Methods

- A pragmatic (or practical) trial seeks to answer the question, "Does an

intervention work under *usual* conditions?"

- An explanatory (or efficacy) trial seeks to answer the question, "Can an intervention work under *ideal* conditions?"

Slide 8: Pragmatic Studies

Key Contextual Characteristics

- Questions from, and important, to stakeholders
- Multiple, heterogeneous settings
- Diverse populations
- Comparison conditions are real-world alternatives*
- Multiple outcomes important to decision and policy makers*

Thorpe KE et al., *Can Med Assoc J*, 2009, 180: E47-57

Tunis SR et al. Practical clinical trials…*JAMA* 2003;290:1624-1632

Glasgow RE et al. Practical clinical trials…*Med Care* 2005;43(6):551-557

Slide 9: The Pragmatic-Explanatory Continuum

Indicator Summary (*PRECIS*)

Describes ten domains that affect the degree to which a trial is pragmatic or explanatory.

1. Participant eligibility criteria
2. Experimental intervention flexibility
3. Practitioner expertise (experimental)
4. Comparison intervention
5. Practitioner expertise (comparison) outcome
6. Follow-up intensity
7. Primary trial outcome
8. Participant compliance
9. Practitioner adherence
10. Analysis of primary

Thorpe KE, et al. *Can Med Assoc J* 2009*; 180,* E47-E57.

Slide 10: PRECIS Spiderweb Figure

[Image]Two figures each showing a circle with 10 lines emanating from the center. The lines are titled the following:

1. Follow-up Intensity
2. Practitioner Expertise (Comparison)
3. Flexibility of Comparison Intervention
4. Practitioner Expertise (Experimental)
5. Flexibility of Experimental Intervention
6. Eligibility Criteria
7. Primary Analysis
8. Practitioner Adherence
9. Participant Compliance
10. Outcomes

In Figure 1, the lines are connected at points near the ends indicating a more pragmatic trial. In Figure 2, the lines are connected at points close to the center indicating a more explanatory trial.
[End Image]

Slide 11: Types of Pragmatic Methods and Evidence Needed: 2R's and "RCT"

- Relevant
- Rigorous and
- Rapid
- Cost informative
- Transparent

Glasgow R, *Annals of Behavioral Medicine, 2008, 35:* 19-25.
Glasgow R, Chambers D. *Clinical and Translational Science*, 2012, 5(1):48-55
http://cancercontrol.cancer.gov/IS/
[Image]San Francisco skyline[End Image]

Slide 12: How to Evaluate Technologies that Outpace Research?

[Image]
A figure showing how standard grants are outpaced by technology.
A timeline going from 2005 to 2011. On the top, is a series of boxes showing at what point major technology innovations occurred: YouTube (2005); iPhone (2007); Android (2008); iPad (2010). On the bottom, is a series of boxes showing the key events of a grant: Grant Submit and Award (2005); Development and Pilot Testing (2006-2007); Recruit and Randomize (2008-2009); Follow-ups (2009-2010); Analyze and Publish (2011). [End Image]

William Riley, NHLBI

Slide 13: Rapid Evidence

- Need rapid learning research—especially for pressing issues such as obesity, HIV, explosion of health care spending, health inequities, and cancer survivorship
- EMRs, and their potential enhancements, make possible "rapid learning health care systems"*
  - *Real-time data on millions of real-world patients in real-world health care settings, treated under usual conditions*

Institute of Medicine, A Foundation for Evidence-Driven Practice: A Rapid Learning System for Cancer Care, 2010. http://www.iom.edu/Reports/2010/A-Foundation-for-Evidence-Driven-Practice-A-Rapid-Learning-System-for-Cancer-Care.aspx
Etheredge L et al, *Health Affairs, Web Exclusive Collection,* w107-w118, doi:10.1377/hlthaff.26.2.w107)

Slide 14: Transparent Evidence on…

- Info needed to *replicate* or implement
- *Resources required*—costs for participants and delivery setting perspectives
- How were settings, staff, and participants selected—(who *was excluded and why*)
- *Adaptation*—changes made to protocol, to intervention, to recruitment, etc.
- *Differences across settings*

Slide 15: Pragmatic Measures—(proposed)

1. Required Criteria
   - Important to stakeholders
   - Burden is low to moderate
   - Broadly applicable, has norms to interpret
   - Sensitive to change
   - Actionable

2. Additional Criteria
- Causes no harm
- Addresses public health goal
- Related to theory or model
- "Maps" to "gold standard" metric or measure

Slide 16: Need for Better and Harmonized Measures

- Most studies use their own measures, often unknown characteristics, and quite different measures of same construct
- Without more standardized measures, difficult to do reviews, syntheses, compare across studies
- Are different purposes of measurement—e.g.:
  - "Gold standard"—when this is primary focus for grant, need "best possible measure", have staff to ensure quality
  - "Practical measure"—for use in busy, low-resource settings; when one of a large set of measures; has to be brief and feasible

Slide 17: D&I and Patient-Reported Measures Initiatives

[Image] Screenshot of GEM-D&I website (https:www.gem-beta.org/GEM-DI)[End Image]
https:www.gem-beta.org/GEM-DI (Grid Enabled Measures)
http://cancercontrol.cancer.gov/IS/resources.html (IS Team Website)

Slide 18: EHR Measures for Primary Care

- In the billions of dollars spent on EHRs in last several years, one thing is missing: Patient-Reported Measures
- Advent of patient-centered medical home and "meaningful use" of EHRs
- *Impossible to provide patient-centered care if no patient measures*, goals, preferences, concerns collected
- With recent advances in measurement, meaningful use incentives, time is right

Slide 19: PATIENT REPORT EHR MEASURES

- Content experts identify 2-3 candidate measures in each of 13 key domains
- Widespread web-based wiki activity: https://www.gem-beta.org/GEM-DI
- "Town Hall" Meeting at NIH: Day 1: town hall; Day 2: invited stakeholder decision makers
- Post Meeting and Beyond: Pilot study followed by pragmatic trial of actual implementation

Estabrooks PA, et al. *J Am Med Inform Assoc* 2012 Jul 1;19(4):575-82.

Slide 20: [Table]

Domain	Final Measure (Source)
1. Demographics	9 items: Sex, date of birth, race, ethnicity, English fluency, occupation, household income, marital status, education, address, insurance status,

	veteran's status. Multiple sources including: Census Bureau, IOM, and *National Health Interview Survey (NHIS)*
2. Overall Health Status	1 item: BRFSS Questionnaire
3. Eating Patterns	3 items: Modified from Starting the Conversation (STC) [Adapted from Paxton AE et al. *Am J Prev Med* 2011;40(1):67-71]
4. Physical Activity	2 items: The Exercise Vital Sign [Sallis R. *Br J Sports Med* 2011;45(6):473-474]
5. Stress	1 item: Distress Thermometer [Roth AJ, et al. *Cancer* 1998;15(82):1904-1908]
6. Anxiety and Depression	4 items: Patient Health Questionnaire—Depression & Anxiety (PHQ-4) [Kroenke K, et al. *Psychosomatics* 2009;50(6):613-621]
7. Sleep	2 items: a. Adapted from BRFSS b. Neuro-QOL (Item PQSLP04)
8. Smoking/Tobacco Use	2 items: Tobacco Use Screener (Adapted from YRBSS Questionnaire)
9. Risky Drinking	1 item: Alcohol Use Screener [Smith et al. *J Gen Int Med* 2009;24(7):783-788]
10. Substance Abuse	1 item: NIDA Quick Screen [Smith PC et al. *Arch Int Med* 2010;170(13):1155-1160]

[End Table]

Slide 21: Pragmatic Implementation Trial

(Fall 2012 - Summer 2013)

- Nine pairs of primary care clinics (18 total): Half FQHC community health centers (NCI), half other PBRN primary care clinics (AHRQ)
  - Each clinic contributes approximately 200 patients
  - Cluster Randomized *pragmatic study*—delayed intervention control—assess at 4 and 8 months
  - Clinics elected to be diverse and at different stages of EHR implementation
  - *Key outcomes are implementation*; creation of action plans; patient behavior change is secondary
  - Final protocol designed collaboratively

Slide 22: Key Points of Collaborative Implementation Trial

- Designing for flexibility and adoption—e.g., varying levels of clinic integration of EHRs, different levels and modalities of decision aids
- WHAT is delivered—e.g., survey, feedback, goal setting, follow-up is STANDARD
- HOW this is delivered is CUSTOMIZED to setting

- Study goal = routine use of survey items, feedback, action planning/goal setting tools and follow-up support

[Image] Map of US showing Implementation trial sites: Oregon, California, Minnesota, Texas, Virginia, North Carolina [End Image]

Slide 23: Evidence Integration Triangle

[Image] Intervention (Program/Policy) (e.g. design; key components; principles guidebook; internal and external validity) has a bi-directional connection to "Practical Progress Measures (e.g. actionable & longitudinal measures)". "Practical Progress Measures" has bi-directional connection to "Participatory Implementation Process" (e.g. stakeholder engagement; team-based science; CBPR; patient centered care). "Implementation Process" has a bi-directional connection to "Intervention (Program/Policy)". Each bi-directional arrow displays the word "Feedback" above it. This completes the circular connection from "Intervention (Program/Policy)" to "Practical Progress Measures" to "Implementation Process" back to "Intervention (Program/Policy)". Two ovals with the words, "Evidence and Stakeholders" are in the middle of the triangle. A circle encompasses the whole triangle and lists the six Multi-level contexts: (1) Intrapersonal/biological; (2) Interpersonal/Family; (3) Organizational; (4) Policy; (5) Community/Economic; (6) Social/Environment/History.[End Image]

Glasgow RE, Green LW, Taylor MV, et al. Am J Prev Med 2012;42:646-54

Slide 24: Realist Perspective

- Answers "contextual" questions, such as "*which intervention components are effective for what outcomes under what conditions when delivered by what staff for what groups*?"
- Contrast with "average effects" approaches

Slide 25: RE-AIM Realist Evaluability Questions

- What percent and what types of participants are likely to *Receive* this program;
- For whom among them is the intervention *Effective*; in improving what outcomes; what broader effects and potential negative consequences?
- What percent and what types of settings and practitioners are likely to *Adopt* this program;
- How consistently are different parts of the program likely to *be Implemented* across settings, clinicians, and participant subgroups…and at what cost;
- And how well is the program and its effects likely to be *Maintained*?

Leviton LC, et al. *Annu Rev Public Health* 2010; 31:213-233.

Slide 26: Pragmatic Science Funding Opportunities

- Dissemination and Implementation Research in Health PAR 10-040
- Small Business Initiative (SBIR and STTR) grants
- NIH Health Care System Collaboratory grants, other NHLBI and NIDDK R18 grants
- NIH research networks—CRN, CVRN, MHRN etc.
- PCORI, CDC and AHRQ grants and networks
- VA Health Services Research grants

Slide 27: Take-Home Points

- There is a pressing need for a DIFFERENT type of research and evaluation—on pragmatic methods, measures and models that produce results more rapidly, and are more relevant to stakeholders
- This field is still emerging, but there is agreement on key common points and goals

- There are many opportunities for this type of research, especially among research networks and for academic-community coalitions to study context